

Application No.: 09/687,278

REMARKS / ARGUMENTS

Remaining Claims

Twenty One (21) claims (Claims 1 and 3 – 22) remain pending in this application through this Amendment. Claims 1, 3, 5, 8, 11, 14, 17, and 21 have been amended herein to more clearly define the invention.

Specifically, Claim 1 is amended to more clearly define that the lowering of the temperature achieved with a cryogenic substance, while Claims 5, 11, and 14 are amended to more distinctly claim "indirectly cooling the contact lens" by contacting the cryogen with the mold, rather than "directly" with the contact lens. This amendment finds support in the specification in the last paragraph on page 4.

Claims 8, 11, 14, and 17 are amended to more accurately claim the polymeric contact lens as a "siloxane-containing," rather than silicon containing. This amendment finds support in the specification in the second full paragraph of page 5.

Further amendments to Claims 14 and 21 in response to Examiner's §112 rejection are described below.

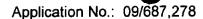
As explained in more detail below, Applicants submit that all claims are in condition for allowance and respectfully request such action.

Rejection of Claims 14 - 16 and 21 under 35 USC §112, second paragraph

Claims 14 - 16 and 21 stand rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 14 is amended in line 5 to clarify a "lens which may separate from the mold and fall" rather than a "falling" lens. This is appropriate because the lens has not yet been separated from the mold, and may not fall, but yet may fall once separated because of the orientation of the mold in the first step of the method. Applicants believe this amendment to address Examiner's §112 rejection in this regard. However, if Examiner disagrees, Applicants would appreciate any suggestions for more appropriate terminology that Examiner may have 1.

¹ Applicants do note and appreciate Examiner's suggestion of "falls" rather than "may fall" in step 1 of the method. However, Applicants are concerned that such terminology would imply that the lens will fall as soon as the mold is oriented in this manner. Such is most likely not the case, as the lens may not yet have been deblocked at this point in the method.



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Claim 21 is amended in accordance with Examiner's kind suggestions for overcoming the §112 rejection.

Therefore, in view of Applicants' claim amendments, Applicants submit that Claims 14 – 16 and 21 are no longer indefinite. Applicants, therefore, respectfully request that this rejection be withdrawn.

Rejection of Claims 1 - 22 under 35 USC §103(a) — Japanese Kokai in view of Hoffman, et al.

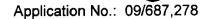
Claims 1 – 22 stand rejected under 35 USC §103(a) as being obvious under Japanese Kokai 1-152,015 (JP '015)in view of US Patent No. 5,607,518 to *Hoffman, et al.*

Applicants respectfully submit that neither JP '015 nor *Hoffman, et al.*, singly or in combination, disclose or suggest "lowering the temperature of the contact lens with a cryogenic substance to a temperature sufficient to reduce adhesion between the lens and the mold."

Specifically, while JP '015 does teach quenching of a recently formed lens having "recessed and projected sections on its surface" (e.g. fresnel lens) with a cryogen, it explicitly teaches that not only does the "lower surface 3b adhered to the mold <u>retains the mold temperature</u>" but the lens is ejected from the mold with "ejecting pins 5 and 6." Any loosening of the lens within the mold is due to a "large local shrinkage 17 ... generated on the upper surface" – and not any reduction in adhesion between the mold and lens surfaces from lowering of the temperature.

While a contact lens in the present invention might undergo slight dimensional changes upon cooling which assist in reducing adhesion (see, e.g. page 6, lines 19-24), the deblocking achieved in the present invention as claimed is a result of reduced "adhesion between the lens and mold" brought about by "lowering the temperature of the contact lens with a cryogenic substance".

Hoffman, et al, also fails to teach "lowering the temperature of the contact lens with a cryogenic substance to a temperature sufficient to reduce adhesion between the lens and the mold." While Hoffman, et al. do teach immersion of the contact lens into a supercritical fluid (SCF), for a SCF to achieve the objectives of the process defined therein, it must have a "temperature of at least 20 °C and a pressure of at least 600 psia." (Col. 3, lines 39-45). Such a fluid is certainly not within the scope of a cryogen, as claimed. In fact, no example



teaches a temperature below 25 °C and <u>no example carried out at a temperature below 30 °C achieved anything but partial and incomplete deblocking². Thus, *Hoffman, et al.* certainly do not teach *lowering* the temperature of the lens in order to reduce adhesion.</u>

Therefore, since the cited combination of prior art does not fairly teach or suggest the claimed invention, Claims 1 – 22 are not rendered obvious by JP '015 in view of *Hoffman, et al.*. Applicants, therefore, respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the foregoing and in conclusion, Applicants submit that the 35 USC §§103 and 112 rejections set-forth in the Office Action have been overcome, and that the pending claims are not indefinite or obvious over the cited art, either individually or in combination. Applicants request reconsideration and withdrawal of the rejection(s) set-forth in the Office Action. Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned.

Please address all correspondence to Novartis Corporation, Corporate Intellectual Property, One Health Plaza, Bldg. 430, East Hanover, NJ 07936-1080. The commissioner is hereby authorized to charge any other fees with may be required under 37 C.F.R. §1.16 and 1.17, or credit any overpayment, to Deposit Account No. 19-0134.

Respectfully submitted.

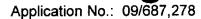
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² While Example VIII teaches a temperature of "about 21 °C," it is important to note that this example does not use a SCF, but instead, is a control sample utilizing 100% IPA to extract the lenses after they are deblocked. Thus, *Hoffman*, et al. teach using higher temperatures than has been used in the art (i.e., the control).



VERSION WITH MARKING TO SHOW CHANGES MADE

In the Claims

Please cancel Claim 2.

Please amend Claims 1, 3, 5, 8, 11, 14, 17, and 21 as follows:

1. (amended) A method for extracting a polymeric contact lens from a mold, the method comprising:

lowering the temperature of the contact lens <u>with a cryogenic substance</u> to a temperature sufficient to reduce adhesion between the lens and the mold to a point where removing the lens will not damage the lens, and

thereafter removing the lens from the mold.

- 3. (amended) The method of claim 2 1 wherein the step of substantially reducing the molecular mobility lowering the temperature of the contact lens comprises directly contacting the contact lens with a the cryogenic substance.
- 5. (amended) The method of claim 2 1 wherein the step of substantially reducing the molecular mobility lowering the temperature of the contact lens comprises indirectly cooling the contact lens by contacting the mold with a the cryogenic substance while the lens is in contact therewith with the mold.
- **8.** (amended) A method for extracting a <u>silicon</u> <u>siloxane</u> containing polymeric contact lens from a mold, the method comprising:

bringing the lens into contact with a cryogenic substance for a time sufficient to lower the temperature of the lens to a temperature sufficient to reduce adhesion between the lens and the mold to a point where removing the lens will not damage the lens.

separating the lens from the mold, and recovering the lens.

11. (amended) A method for extracting a <u>silicen siloxane</u> containing polymeric contact lens from a mold, the method comprising:

indirectly cooling the contact lens by bringing the mold into contact with a cryogenic substance for a time sufficient to lower the temperature of the lens to a temperature sufficient to reduce adhesion between the lens and the mold to a point where removing the lens will not damage the lens,

separating the lens from the mold, and recovering the lens.

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14. (amended) A method for extracting a <u>silicon</u> <u>siloxane</u> containing polymeric contact lens from a mold, the method comprising:

orienting a contact lens bearing mold upon a carrier such that the contact lens may fall from the mold;

situating a contact lens collector so as to collect a falling contact lens which may separate from the mold and fall;

indirectly cooling the contact lens by causing the mold to come into intimate contact with a cryogenic substance; causing separation of the lens from the mold; and collecting the lens.

17. (amended) A method for manufacturing a silicon siloxane containing polymeric contact lens from a mold, the method comprising:

bringing two mold halves together to form a lens mold;

filling the mold with an uncured polymer;

curing the polymer in the mold;

separating the mold halves from one another;

bringing the mold half bearing the contact lens into contact with a cryogenic substance for a time sufficient to lower the temperature of the lens to a temperature sufficient to reduce adhesion between the lens and the mold half to a point where removing the lens will not damage the lens;

separating the lens from the mold half, and recovering the lens.

21. (amended) A deblocking apparatus according to claim 20 wherein said <u>means for</u> cooling means comprises a reservoir in said lens mold for receiving a cryogent <u>cryogen</u> therein.